DEPARTMENT OF STATE HEALTH SERVICES
CENTRAL OFFICE INSTITUTIONAL REVIEW BOARD
APPLICATION FOR CONTINUING REVIEW OR STUDY CLOSURE

Protocol #: _____-_____-_____

Project Title: _____

Principal Investigator(s): (Give address for correspondence about approval.)

_____	_____	_____
(Name -- type or print)	Address	E-mail Address

If funded, indicate title of grant and funding agency:

_____

Date of initial IRB review: _____ Date of last IRB review: _____

DHHS regulations require an annual review of continuing projects at least once per year. This review must take place on or before the one-year anniversary of the previous IRB review, regardless of when the research project itself began. Investigators must also report to the IRB any planned changes in the protocol of the study because these may affect the protection of human research participants. Please complete items 1 through 8 as they apply to your project during the period following your last IRB review.

Please attach your current Research Proposal (See Section "Topics to Address in the Research Proposal") and your current Consent Form(s).

1. Has the research begun? ___ Yes ___ No
2. Enrollment of subjects ongoing? ___ Yes ___ No
3. Date that first subject was enrolled: _____
4. Number of participants originally proposed: _____
   Number actually enrolled as of this date: _____
   Number of subjects enrolled in the past 12 months: _____
   Number withdrew or dropped out: _____
   Number dropped out because of adverse study events: _____
   (Explain in #9)
5. Study interventions ongoing ___ Yes ___ No
   (e.g. Surveys, questionnaires, etc)
6. Is this a Final Report? ___ Yes ___ No
   (Protocols can be inactivated when all research activities, including data analysis, have been completed).

7. Informed Consent:
   Was consent obtained for all subjects? ___ Yes ___ No
   Did all subjects receive a copy of the signed consent form? ___ Yes ___ No
   Where are signed consent forms stored? _____
   (Site: Bldg and room number)
   Did you encounter any problems in obtaining consent? ___ Yes ___ No
   If yes, please describe: _____
   Is the person obtaining consent approved by the IRB? ___ Yes ___ No
   If no, please describe: _____
8. Have any changes been made to the following:
   Protocol? ___ Yes ___ No
   Consent? ___ Yes ___ No
   Questionnaires? ___ Yes ___ No
   Study Interventions? ___ Yes ___ No
   New Investigators? ___ Yes ___ No
   If yes to any of above, please describe on a separate sheet.
9. Has any new scientific information (such as recently identified risks of participating in research of this type or new treatment/alternative approaches been found) since the last IRB approval? ___ Yes ___ No
   If yes, please describe on a separate sheet this new information and how the risk to subjects in your study may be affected by these findings.
10. During the past 12 months please indicate the following:
    Number of serious adverse events: _____
    Number of deaths: _____
    Were the events listed above promptly reported to the IRB? ___ Yes ___ No
    If no, please explain: _____
11. Summarize Study Activities and Findings to Date. (Attach resulting publications).

I/we certify that the statements and attachments concerning this research are true.

_____ _____
Signature of Principal Investigator Date

REVIEWED and APPROVED:

The information provided has been reviewed and approved by the DSHS Central Office Institutional Review Board (CO-IRB) for the Protection of Human Subjects in Research for compliance with federal regulations for continuing review.

_____ _____
Signature of IRB Chair or Acting Chair Date of Review